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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,146	03/17/2004	Nancy Jean Britten	PC027932A	5036

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PHARMACIA & UPJOHN
7000 Portage Road
KZO-300-104
KALAMAZOO, MI 49001

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,146	BRITTEN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27 and 33-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27 and 33-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed March 28, 2008 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claims 25-27 and 33-58 are pending in this application.

Terminal Disclaimer

The terminal disclaimers filed on March 28, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/795,191, 10/903,662 and 10/909,050 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Specification

The word "pegicol-5-oleate on page 29 is misspelled. The correct spelling is "peglicol-5-oleate". Appropriate correction is required.

Claim Objections

Claims 43 and 58 are objected to because of the following informalities: the word "pegicol-5-oleate is misspelled. The correct spelling is "peglicol-5-oleate". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment, does not reasonably provide enablement for prevention of an inflammatory condition of the udder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the

state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in pharmacology and molecular biology is high, the results of experiments in these subject matter areas are frequently unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Claim 26 is drawn to a composition for intramammary infusion to an udder of a milk producing animal for treatment and/or prevention of an inflammatory condition of the udder.

The Nature of the Invention: The nature of the invention is a composition for treatment and/or prevention of an inflammatory condition of the udder, such as mastitis (see claims).

The State of the prior Art and predictability: While the state of the art is relatively high with regard to **treatment** of inflammatory conditions of the udder and mastitis, the state of the art with regard to **prevention** of such disorders is underdeveloped. The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of these disorders with reasonable predictability makes practicing the invention unpredictable and would require undue experimentation.

Guidance and working examples: The specification gives guidance for treatment of conditions drawn to inflammation and infection of the afflicted organ, such as an udder, however, it does not provide adequate guidance

as to how one would prevent an inflammatory condition of an udder or mastitis with reasonable assurity.

Thus the specification fails to provide sufficient support of the use of the composition of the claims for the prevention of inflammatory conditions of the udder and mastitis. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of inflammation of an udder or mastitis by administration of the claimed composition.

Therefore, a method of **preventing** the prevention of inflammatory conditions of the udder and mastitis administering the pharmaceutical composition of claim 25 is not considered to be enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites the limitation "the composition of claim 25 wherein the polyglycolized glyceride is pegicol-5-oleate" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim because there is not a polyglycolized glyceride recited in claim 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-27 and 33-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patil et al. U.S. Patent No. 4,299,501 and Ranbaxy Laboratories LTD. (hereinafter referred to as Ranbaxy) WO 02/17923.

Patil et al. teach a composition comprising peglicol-5-oleate (A), microcrystalline wax (B) (see example 4, column 4) mineral oil (C) (column 3, lines 53-54; column 4, lines 44-45) along with an emulsifier (as in instant claim 57) (column 3, lines 3-15). The composition included other ingredients such as pharmaceutical materials (column 3, lines 8-9). Ranbaxy teach topical delivery of cyclooxygenase-2 (COX-2) enzyme inhibitors (page 4, lines 16-18), such as celecoxib, valdecoxib, rofecoxib, varecoxib, parecoxib and the like (page 6 line 21 to page 7, line 2). It would have been obvious to one having ordinary skill in the art to substitute any of the COX-2 enzyme inhibitors of Ranbaxy for the "pharmaceutical material" of Patil et al. to arrive at a pharmaceutical composition comprising the amphipathic oil (peglicol-5-oleate), a non-aqueous carrier (mineral oil) and microcrystalline wax. The prior art does not teach the amphipathic oil that is water dispersible and ethanol insoluble, and is a polyglycolized glyceride that is prepared by an alcoholosis reaction of natural triglycerides with polyethylene glycol, however, claim instant claim 58 indicates that all of these properties are contained in the peglicol 5-oleate and as such, the characterization described in instant claims 25-27 and 33-58 are obvious over the peglicol 5-oleate of Patil et al.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed; however, the intended use of the claimed

composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Regarding the dosages instantly claimed, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe inflammation would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to have used dosages of COX-2 inhibitors in a concentration of 0.01 to 1000 mg/ml

Further, regarding the amounts of amphipathic oil, microcrystalline wax and non-aqueous carrier, the specific safe and effective amount will be vary, with such factors as the particular COX-2 inhibitor being dispersed into the composition, the physical condition of the patient, the duration of treatment, the

nature of the concurrent therapy (if any), the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. It would have been obvious to vary the amounts of amphipathic oil, microcrystalline wax and non-aqueous carrier. Regarding instant claim 51, 52 and 58, drawn to inter alia, cottonseed oil, Patil et al. teach mineral oil as a non-aqueous carrier. It would have been prima facie obvious to substitute one non-aqueous carrier for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious. Patil et al. showed that the amphipathic oil, peglicol 5-oleate combined with the nonaqueous carrier mineral oil and microcrystalline wax is an effective carrier for pharmaceutical material and Ranbaxy showed that COX-2 enzyme inhibitors are effective when administered topically. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the carrier taught in Patil et al for the carrier of Ranbaxy for the predictable result of forming a stable composition for administration of COX-2 inhibitors, such as celecoxib.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-27 and 33-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 12/037556.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a pharmaceutical composition comprising an anti-inflammatory agent, such as a COX-2 inhibitor and a vehicle that comprises an amphipathic oil (Labrafil ™), microcrystalline wax, and a non-aqueous carrier. The claims of Application No. 12/037556 are drawn to a pharmaceutical composition comprised of an antibacterial agent and a COX-2 inhibitor in a non-aqueous vehicle and microcrystalline wax and an (amphipathic) oil, such as Labrafil™. The comprising claim language of the instant claims does not exclude the antibacterial agent of the conflicting claims. Regarding the polyglycolized glyceride prepared by an alcoholosis reaction of natural triglycerides with polyethylene glycols of instant claims 40-43, the conflicting claims teach Labrafil ™. The portion of the specification of the conflicting case that supports the

claims teaches that "Labrafil™ refers to oils comprising polyglycolized glycerides prepared by an alcoholosis reaction of natural triglycerides with polyethylene glycols" (page 11, lines 1-3). Regarding the concentration of the instant composition, although not specifically claimed in the conflicting case, the portion of the conflicting specification that supports claims 1-7 teach the same anti-inflammatory agents in the same concentration (see page 19, lines 27-30). It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

July 31, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614